

Submission of Knowledge Ecology International (KEI) to the WIPO Standing Committee on the Law of Patents

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In November 2001, the World Trade Organization (WTO) Ministerial Conference in Doha, Qatar adopted the Doha Declaration on the TRIPS Agreement and Public Health affirming that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. This landmark declaration marked a watershed in global trade governance, by singling out public health and in particular, health technologies, from other trade-related issues. The Doha Declaration reiterated that health technologies are not just another commodity and may be differentiated from other inventions as underscored by paragraph four of the Declaration,

"the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all".

The Doha Declaration was precipitated by a request made by the African Group in April 2001 for the WTO to hold a special session of the TRIPS Council to clarify the relationship between intellectual property and access to medicines. In its request, the African Group observed,

"[a]s the recent upsurge of public feelings and even public outrage over AIDS medicines has shown, there is now a crisis of public perception about the IPR system and about the role of TRIPS which is leading to a crisis of legitimacy for TRIPS.

Whilst this storm is raging outside the WTO, and legitimately so, we as Members inside the WTO cannot shut our eyes and ears. Each of us, from developing and developed countries, must respond, and respond adequately and appropriately."

Nearly ten years on from Doha, it is perhaps appropriate that the African Group and the Development Agenda Group (DAG) tabled their paper on a work program for patents and health (SCP/16/7) at the 16th session of the Standing Committee on the Law of Patents (SCP) with the over-arching objective that the, 'patent system should be consistent with fundamental public policy priorities, and in particular the promotion and protection of public health'. This objective is further fleshed out in the context session of the African Group/DAG submission,

"The WHO Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property adopted in 2008 states that while international IP agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries, they may face obstacles in the use of flexibilities. Thus, there is a need to address this problem and remove obstacles faced by developing countries in making full use of the public health related flexibilities. The GSPOA also states that IPRs should not prevent Member States from taking measures to protect public health, and that international negotiations on issues relating to IPRs and health should be coherent in their approaches to the promotion of public health.

In order to protect public health, the flexibilities and safeguards contained and allowed by the TRIPS Agreement would need to be incorporated in the national legislation. There is equally the need to ensure that international commitments, including regional and bilateral arrangements, do not restrict these flexibilities and safeguards. Moreover, these safeguards and flexibilities have to be workable in practice, particularly with respect to ensuring access to medicine."

To preface our contribution on patents and health, we observe that recommendation 14 of WIPO Development Agenda (<http://www.wipo.int/ip-development/en/agenda/recommendations.html>) states:

"Within the framework of the agreement between WIPO and the WTO, WIPO shall make available advice to developing countries and LDCs, on the implementation and operation of the rights and obligations and the understanding and use of flexibilities contained in the TRIPS Agreement."

We note that technical assistance experts often fail to distinguish between compulsory licenses that are granted under the procedures of Part II of the TRIPS, concerning patent rights, and those granted under Part III of the TRIPS, concerning the remedies for infringement of those rights. For example, the most commonly used mechanisms for obtaining a compulsory license in the United States are those associated with Part III of the TRIPS, including in particular Article 44 of the TRIPS. Under the structure of the TRIPS agreement, Article 44 compulsory licenses are not subject to the restrictions that exist for Article 30 and 31 of the TRIPS, an issue not explored in the experts reports. Consequently, we support the African Group/DAG request for the International Bureau of the World Intellectual Property Organization (WIPO) to "Organize a technical workshop on state practice involving the compulsory licensing of medical technologies, including the application of TRIPS Articles 30, 31 and 44."

KEI supports the African Group/DAG proposal for the International Bureau to "commission a framework study by independent experts" to document state practice on compulsory licensing including the provision of empirical data on the royalty rates set in each case and an "examination on the extent to which countries use exhaustion of rights to allow parallel trade in medicine".

In addition, under the mandate of recommendation 14, we request the International Bureau to undertake technical studies on the following:

- Current implementation of Paragraph 7 of the Doha Declaration on TRIPS and Public Health, regarding patents in LDCs,
- The methods of implementing Paragraph 6 of the Doha Declaration
- In the area of patent quality, WIPO should also consider gathering statistics and creating a database of challenges to patent validity, so that it is easier for residents of one country to learn about a patent validity dispute in another country, and possibility to even consider patent reexamination when claims are overturned in another country.

The discussion of the relationship between patents and health in WIPO's patent committee is timely as nearly ten years from the passage of the Doha Declaration, negotiations on the Political Declaration for the United Nations High Level Meeting (HLM) on Non-Communicable Diseases (NCDs) to be held in New York on 19-20 September 2011 have witnessed the European Union and the United States endeavoring to purge all references to the Doha Declaration.

KEI observes that the Doha Declaration explicitly states the following,

"In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."

As KEI noted in its analysis [1] of the NCD negotiations in New York,

"The 2001 Doha Declaration came about largely because of the very visible crisis surrounding access to patented medicines to treat AIDS. The Bush Administration and the European Commission sought to narrow the understanding about health and intellectual property so it only applied to AIDS, or a limited set of infectious diseases. That effort failed in 2001 and again in 2003, during an interpretation of another section of the agreement. Since then, the U.S. and the European Commission have generally accepted references to the Doha Declaration on TRIPS and Public Health in World Health Resolutions, such as WHA61.21, in 2008, and in several bilateral and regional trade agreements, including in the final text of the AntiCounterfeiting Trade Agreement (ACTA), which was completed in December of 2010. However, in a number of cases, the US and the EU have also asserted that the Doha Declaration is in fact limited to AIDS, infectious diseases or epidemics. These backtracking interpretations have always been strategic, when the US and the EU wanted to push back against a developing country effort to use compulsory licensing of patents for anything other than drugs for AIDS."

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The proposed framework study of independent experts that the African Group and the Development Agenda Group requested to examine the challenges faced by developing countries and LDCs in making full and effective use of public health related flexibilities should analyze why the European Union and the United States would seek to eliminate all references to the Doha Declaration in the Outcome Document United Nations High Level Meeting on Non-Communicable Diseases (NCDs). We posit that the European Union and the United States endeavor to purge references to the Doha Declaration is motivated by the desire to rewrite history by asserting that the 'access to medicines' provisions in the Doha Declaration do not apply to medicines for cancer and other non-communicable diseases and to raise doubts about the application of other elements of the Doha Declaration, including paragraphs 5, 6 and 7 to non-communicable diseases, if not legally, at least politically. In WIPO's documentation of state practice on compulsory licensing, the International Bureau may wish to catalog the following two compulsory licenses recently issued in the United States, for contact lenses [2] as well as a device to treat aortic valve stenosis [3].